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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,715

11/13/2003

Akira Suyama

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08/24/2006

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,715	<b>Applicant(s)</b> SUYAMA ET AL.	
	<b>Examiner</b> Frank W. Lu	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/03 and 11/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 17-25 in the reply filed on June 2, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on two applications, 11-283148 and 11-283437, filed in Japan on October 4, 1999. Although the examiner who worked with the parent case 09/872,881 indicated that certified copies of these application have been obtained, the examiner cannot locate these certified copies in eDAN.

### ***Specification***

3. The disclosure is objected to because of the following informalities: (1) since US Application No. 09/872,881 now has been abandoned, applicant is required to update this information in the first sentence of the specification; and (2) Figures 9 and 13A contain nucleotide sequences with more than 10 nucleotides. However, there are no SEQ ID Nos in Figures 9 and 13A, and BRIEF DESCRIPTION OF THE SEVERAL VIEWS of the specification does not describe these SEQ ID Nos.

Appropriate correction is required.

***Claim Objections***

4. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because claim 18 includes all limitations recited in claim 20. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. New Matter

Claims 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 17-25 have been added to this application. However, the specification fails to define or provide any disclosure to support these newly added claims. Furthermore, in applicant's remarks filed on November 13, 2003, applicant does not indicate which part in the specification supports these claims.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual

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inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT “NEW MATTER” IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*” (emphasis added).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 17 recites the limitation “nucleic acid constructing the flag” in step (e) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “nucleic acid constructing the flag” in step (a) to (d) of the claim. Please clarify.

10. Claim 17 is rejected as vague and indefinite in view of the phrase “the single-stranded flag sequence obtained by the encode reaction” in step (f) because step (e) does not indicate that a single-stranded flag sequence is produced by an encode reaction. Please clarify.

11. Claim 17 is rejected as vague and indefinite in view of the phrase “the nucleic acid molecule obtained by the decode reaction” in step (g) because step (f) does not indicate that a nucleic acid molecule is produced by a decode reaction. Please clarify.

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12. Claim 18 is rejected as vague and indefinite. Since claim 18 does not indicate that the groups of A1 to An, B1 to Bn, F1 to Fn, F1' to Fn', S1 to Sn, S1' to Sn', and D01 to D0n have the same properties as A, B, F, F', S and S', it is unclear how said probe A can be any one of the probe groups A1 to An (n is an integer of 2 or more), said probe B can be any one of the probe groups B1 to Bn (n is an integer of 2 or more), said partial sequence F can be any one of partial sequences F1 to Fn, said sequence F' can be any one of the sequences F1' to Fn' (n is an integer of 2 or more), said partial sequence S can be any one of partial sequences S1 to Sn (n is an integer of 2 or more), said sequence S' can be any one of the partial sequences S1' to Sn' (n is an integer of 2 or more), said D0 can be any one of D01 and D0n (n is an integer of 2 or more), said D1 can be any one of D01 to D0n (n is an integer of 2 or more), and said probe (A+B) can be any one of probe groups (A1+B1) to (An+Bn) (n is an integer of 2 or more). Please clarify.

13. Claim 19 recites the limitation "the single-stranded sequence encoded to a PCR" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase "single-stranded sequence encoded to a PCR" in claims 17 and 18. Please clarify.

14. Claim 19 is rejected as vague and indefinite because it is unclear "the single strand" in step (iv) is a single-stranded PCR product in step (iii) or the single-stranded sequence encoded to a PCR. Please clarify.

### ***Conclusion***

15. No claim is allowed.

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16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

August 17, 2006



FRANK LU  
PRIMARY EXAMINER